

REMARKS

In the Office Action dated September 19, 2008, claims 1-16 are pending. Claims 5 and 8-14 are withdrawn from consideration. Claims 15-16 are allowed. Claims 1-4 and 6-7 are deemed patentable over McIntosh et al. (U.S. Patent No. 6,767,896 B1) in view of Jones et al. (U.S. 2005/0271589 A1) to the extent that these claims read on the elected species of SEQ ID NO: 4. However, claims 1-4 remain provisionally rejected on the ground of non-statutory obviousness-type double patenting as allegedly unpatentable over claims 2, 5-6, 12-13, 15-21, 38-41, 43, 45, 47 and 49 of co-pending Application Serial No. 10/537,088. Claims 1-4 and 6-7 are also objected to for not conforming in scope to the elected species of SEQ ID NO: 4.

This Response addresses each of the Examiner's rejections and objections. Applicants therefore respectfully submit that the present application is in condition for allowance. Favorable consideration of all pending claims is therefore respectfully requested.

Amendments to Claims

Claims 1-2 have been amended, *inter alia*, to define the side chain modifications at a non-Cys residue by reciting that "and/or Pro has been replaced with 4-hydroxyproline, and/or Tyr is substituted with 4-methoxy tyrosine." Support for this amendment is found in the previous version of claim 3 and in the specification, e.g., Table 4 on page 34, for example. Claims 1-2 have also been amended to delete references to "ester" and "prodrug".

Claims 3-5 have also been amended.

Withdrawn claim 11 is amended to include a reference to allowable claims 15-16.

Withdrawn claims 8-10 and 12-14 are canceled.

Claims 17-21 are added. Claim 17 finds support in previous claims 9 and 11, for example, and defines the conditions being treated as "acute, chronic and/or neuropathic pain,

migraine or inflammation". Claims 18-19 and 20-21 depend from claims 17 and 11, respectively, and find support in previous claims 10 and 12, for example.

No new matter is introduced by the foregoing amendments.

Provisional Non-Statutory Double Patenting

Applicants respectfully submit that several of the claims of the '088 application referenced by the Examiner have been canceled, and that the '088 application has been allowed. Applicants note that the rejection is provisional because none of the allegedly conflicting claims have been issued.

Applicants further note that the present application and the '088 application are national phase applications under §371 based on International Applications filed on the same date. In the event that any conflicting claims issue from the '088 application, Applicants intend to file a terminal disclaimer to overcome a properly raised non-statutory double patenting rejection.

Objection to Claims, Request for Examination of Additional Peptide Species

Claims 1-4 and 6-7 are objected to for not conforming in scope to the elected species of SEQ ID NO: 4.

In light of the fact that the elected peptide species of SEQ ID NO: 4 is free of prior art and potentially allowable, Applicants respectfully request that the Examiner include additional peptide species in the examination. Specifically, the currently presented peptide species represent a defined group of peptides having substantial structural similarity with the elected peptide of SEQ ID NO: 4. In comparison with SEQ ID NO: 4, the peptides presently encompassed by amended claims 1-5 permit a DpGlu residue (instead of a pGlu) at the N-

terminus, a 4-methoxy tyrosine (instead of Tyr), a Proline (instead of a 4-hydroxyproline), and a D-Cys (instead of Cys). Applicants respectfully submit that the substitutions involved in these additional peptide species are fairly conservative substitutions, and these additional peptides share special technical features, e.g., substantial structural similarity, with the elected peptide of SEQ ID NO: 4. Further, Applicants respectfully submit that the reference to Balaji et al. (*J. Biol. Chem.* 275: 39516-22, 2000), which the Examiner has relied upon in making the Restriction Requirement final, does not disclose or suggest any of these additional peptide species.

Accordingly, Applicants respectfully request withdrawal of the objection to the claims and examination of the peptide species currently presented.

Request for Rejoinder of Method Claims

Applicants respectfully submit that where product claims are elected and are found allowable, the withdrawn process claims that depend from the elected allowable product claims should be rejoined.

In the present case, the Examiner has acknowledged that claims 15-16 are allowable. It is believed that claims 1-5 are also allowable. Applicants have amended withdrawn claim 11, and have presented new claims 17-21, all drawn to methods based on administration of products which Applicants believe to be allowable.

Applicants further respectfully submit that the methods of claims 11 and 17-21 are also fully supported by the specification, including the experimental data described on pages 35-39, for example.

Therefore, rejoinder and allowance of claims 11 and 17-21 are respectfully requested.

Conclusion

In view of the foregoing amendments and remarks, it is firmly believed that the present application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to be 'Xiaochun Zhu', written in a cursive style.

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